

Arguments/Remarks

Claims 1-11, 13-15, and 21-24 are currently pending. All of the claims presently stand rejected. Claims 2, 4-5, and 14-15 have been amended and Claims 16-20 have been cancelled. None of the amendments constitute new matter.

Rejections Under 35 U.S.C. 112

The claims 14-22 have been rejected under 35 U.S.C. 112, first paragraph as not being enabled by the specification. More particularly, the Examiner states with regard to claim 14, that, "The specification, while being enabling for a method of treating breast tumor comprising the step of administering a compound of formula (I), does not reasonably provide enablement for a method of treatment of neoplastic diseases and immune system disorders generally." Applicants have limited the claim accordingly. Withdrawal and reconsideration are requested.

The Examiner has also rejected claims 2, 4, and 5 under 35 U.S.C. 112 second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicants regard as their invention. Applicants have amended the claims per the Examiner's suggestions, and have deleted the objectionable terms in order to traverse the rejections. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. 103

The Examiner has rejected claims 1-3, 10-11, and 13-22 under 35 U.S.C. 103(a) as being obvious over WO 04/074244 to Davis-Ward, et al. More particularly, the Examiner states, "It has been held that a prior art disclosed genus of useful compounds is sufficient to render a prima facie obvious a species falling within a genus."

Applicant disagrees. The Examiner has not established a *prima facie* case of obviousness. The Federal Circuit recently addressed obviousness of closely-related chemical structures in *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492. F.3d 1350 (Fed. Cir. 2007). Specifically citing their decision of *In re Deuel*, 51 F3d 1552, the Court stated, "A known compound may suggest its homolog, analog, or isomer because such compounds 'often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties'." The Court clarified however, "that in order to find a prima facie case of unpatentability in

such instances, a showing that the 'prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention' was also required."

The Court further held in *Takeda*, "Thus in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish a prima facie obviousness of a new claimed compound."

Still further, the CAFC has further elucidated the obviousness factors for chemical structures in *Elsai v. Dr. Reddy's Laboratories* (533 F.3d 1353) (Fed. Cir. 2008). The CAFC discussed the *Graham* factors in new chemical composition cases, stating, "Post-KSR, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound."

It is therefore necessary that in order to establish a prima facie case of obviousness for a chemical composition of matter, a lead compound must be identified from the prior art, as well as a showing that the prior art would have suggested making the specific molecular modifications necessary to achieve the claimed invention.

In the present case, the Examiner has neither identified a "lead compound," nor identified a teaching in the art which would lead one of skill in the art to make the modifications to arrive at the claimed invention. The Examiner has cited examples 3 and 5 of Davis-Ward, and the genus generally. None of the compounds disclosed in Davis-Ward are substituted at the R10 position of the presently claimed invention (the ortho position on the phenyl ring). Further, the Examiner has not suggested any reason why one of skill in the art would make the modifications necessary to arrive at the presently claimed compounds. Absent such an analysis, the Examiner has not made a prima facie case of obviousness. Withdrawal and reconsideration of the rejection is respectfully requested.

Double Patenting Rejection

The Examiner has rejected claims 1-11 and 13-22 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 4, and 7-9 of copending application No. 10/507,060. Upon indication of allowable subject matter, applicants will appropriately address the double patenting rejection.

Should the Examiner have any questions, please contact the undersigned attorney.

Respectfully submitted,

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